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ELECTION UNDER 35 USC §121
Examining Group 1633
Patent Application
Docket No. USF.T192XC1
Serial No. 10/544,145

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Scott D. Long
Art Unit : 1633
Applicant : Shyam S. Mohapatra
Serial No. : 10/544,145
Filed : December 22, 2006
Confirm. No. : 1541
For : Chitosan-Microparticles for IFN Gene Delivery

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ELECTION UNDER 35 USC §121

Sir:

Applicant requests that the period for response be extended one month through and including January 19, 2010, the fees for which have been paid at the time this Election was filed.

In response to the written Restriction Requirement dated November 18, 2009 in the above-identified patent application, Applicant hereby elects to prosecute the invention of Group II (claims 10, 12, 16, 24, 30-32, 39, 43, and 47), with traverse.

Applicant notes that 37 CFR §1.475(b) is inclusive, as opposed to exclusive, *i.e.*, §1.475(b) sets forth categories of invention that will be considered sufficient to have unity of invention and does not state that only the recited categories will have unity. Furthermore, Applicant submits that the technical feature of claim 1 makes a contribution over the cited reference, Plank *et al.* (US 2002/0086842). The cited paragraph of Plank *et al.* (paragraph

[0021]) indicates that “the vector may comprise as such a functional group one or more oligo- or polycationic components to form a polyplex ... [s]uch cationic compounds may for example, but not exclusively, be ... poly(amido amine) dendrimers chitosan” and “[a]nother possibility refers to an assembly of the nucleic acid molecule(s) with one or more lipidic, preferably cationic lipidic components to form a lipoplex.” Applicant respectfully submits that paragraph [0021] of Plank *et al.* does not teach or suggest a nanoparticle comprising a complex of chitosan, or a chitosan derivative; a lipid; and a polynucleotide, wherein said nanoparticle induces production of less interleukin-6 in respiratory epithelium compared to a particle comprising a complex of the chitosan, or chitosan derivative, and the polynucleotide without the lipid.

As stated by the Federal Circuit in *Net Moneyin, Inc. v. Verisign, Inc.*, No. 2007-1565, decided October 20, 2008):

Section 102 embodies the concept of novelty—if a device or process has been previously invented (and disclosed to the public), then it is not new, and therefore the claimed invention is “anticipated” by the prior invention. As we have stated numerous times (language on which VeriSign relies), in order to demonstrate anticipation, the proponent must show “that the four corners of a single, prior art document describe every element of the claimed invention.” *Xerox*, 458 F.3d at 1322 (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)). This statement embodies the requirement in section 102 that the anticipating invention be “described in a printed publication,” and is, of course, unimpeachable. But it does not tell the whole story. Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

The meaning of the expression “arranged as in the claim” is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order. In such instances, a reference that discloses all of the claimed ingredients, but not in the order claimed, would not anticipate, because the reference would be missing any disclosure of the limitations of the claimed invention “arranged as in the claim.” But the “arranged as in the claim” requirement is not limited to such a narrow set of “order of limitations” claims. Rather, our precedent informs that the “arranged as in the claim” requirement applies to all claims and refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a particular order. The test is thus more

accurately understood to mean “arranged or combined in the same way as in the claim.”

In the case of the instantly claimed invention, Applicant respectfully submits that Plank *et al.* fail to teach the claimed elements “arranged or combined in the same way as in the claim.” Particularly, Applicant notes that Plank *et al.* fail to teach “a complex of chitosan, or a chitosan derivative; a lipid; and a polynucleotide” and one of ordinary skill in the art would not at once envisage the claimed complex of chitosan, or a chitosan derivative, and a lipid, and a polynucleotide from the cited reference. Moreover, Plank *et al.* fail to provide an enabling disclosure, as the reference does not teach how to make the complex recited in claim 1 of the subject application.

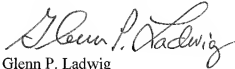
Furthermore, the Restriction Requirement indicates that “Plank *et al.* indicate that these compositions are nanoparticles.” Applicant respectfully submits that any reference to a “nanoparticle” in Plank *et al.* does not refer to “a complex of chitosan, or a chitosan derivative; a lipid; and a polynucleotide” as recited in claim 1. For example, references to specific “nanoparticles” in paragraphs [0004], [0028], [0030], [0035], [0189], [0194], and [0357] in Plank *et al.* are not to the complex recited in claim of the subject application. Thus, each of the claimed elements is not taught by the cited reference in the same manner as “arranged or combined” in the claim.

It is also unclear what teaching of Plank *et al.* is relied upon for the teaching of an induced production of less interleukin-6 in respiratory epithelium compared to a particle comprising a complex of the chitosan, or chitosan derivative, and the polynucleotide without the lipid, as recited in claim 1 of the subject application.

Accordingly, Applicant respectfully requests withdrawal of the Restriction Requirement.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Glenn P. Ladwig". The signature is fluid and cursive, with the first name "Glenn" and last name "Ladwig" clearly distinguishable.

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